510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K121608

FEB 15 2013

1. Submitter Name, Address, Contact

Ortho-Clinical Diagnostics, Inc.
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(585) 453-4041
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2. Preparation Date

510(k) prepared: January 23, 2013

3. Device Name

Trade or Proprietary Names:
VITROS® Immunodiagnostic Products 25-OH Vitamin D Total Reagent Pack
VITROS® Immunodiagnostic Products 25-OH Vitamin D Total Calibrators

4. Regulatory information

a. Regulatory Section
21 CFR 862.1825 Vitamin D Test System
21 CFR 862.1150 Calibrators

b. Classification
Class II

c. Product Code
MRG
JIT

d. Panel
Chemistry (75)

5. Intended Use

a. Intended Use(s):

See Indications for Use

b. Indications for Use

VITROS Immunodiagnostic Products 25-OH Vitamin D Total Reagent Pack:

For *in vitro* diagnostic use only

For the quantitative measurement of total 25-OH vitamin D in human serum using the VITROS ECi/ECiQ Immunodiagnostic Systems, the VITROS 3600 Immunodiagnostic System and the VITROS 5600 Integrated System.

The results of the VITROS 25-OH Vitamin D Total assay are used in the assessment of Vitamin D sufficiency. Assay results may be used in conjunction with other clinical or laboratory data to assist the clinician in patient management.

VITROS Immunodiagnostic Products 25-OH Vitamin D Total Calibrators:

For *in vitro* diagnostic use only.

For use in the calibration of the VITROS ECi/ECiQ Immunodiagnostic Systems, the VITROS 3600 Immunodiagnostic Systems and the VITROS 5600 Integrated System for the quantitative measurement of total 25-OH vitamin D in human serum.

6. Device Description:

The reagent pack consists of:

- wells coated with antibody against 25-OH Vitamin D
- conjugate reagent consisting of HRP-25-OH VitD, buffer and 0.5% Proclin 950
- dissociation reagent consisting of EDTA buffer, surfactant and 0.5% Proclin 950

The Calibrators consist of:

1 set of VITROS 25-OH Vitamin D Total Calibrators 1 and 2 (liquid, 25-OH Vitamin D in human serum with antimicrobial agent, 2.0 mL); nominal values 28 and 120 ng/mL (70 and 300 nmol/L)

7. Device Description

The VITROS Immunodiagnostic Products Vitamin D test system comprises three main elements:

1. The VITROS Immunodiagnostic range of products. In this case the VITROS Immunodiagnostic Products 25-OH Vitamin D Total Reagent Pack and the VITROS Immunodiagnostic Products 25-OH Vitamin D Total Calibrators are required to perform a VITROS Vitamin D test.
2. The VITROS Immunodiagnostic and Integrated Systems: Instrumentation, which provides automated use of the immunoassay kits.

The VITROS ECi/ECiQ Immunodiagnostic System was cleared for market by a separate 510(k) pre-market notification (K962919). This product was updated to the VITROS ECiQ Immunodiagnostic System by addition of a flat panel monitor with an accompanying articulating arm, cosmetic changes to the instrument cabinetry, and with FDA notification in January of 2004.

The VITROS 3600 Immunodiagnostic System: Instrumentation, which provides automated use of the immunoassay kits. The VITROS Immunodiagnostic System was cleared for market by a separate 510(k) pre-market notification (K083173).

The VITROS 5600 Integrated System: Instrumentation, which provides automated use of the immunoassay kits. The VITROS Integrated System was cleared for market by a separate 510(k) pre-market notification (K081543).

3. Common reagents used by the VITROS System in each assay: The VITROS Immunodiagnostic Products Signal Reagent and VITROS Immunodiagnostic Products Universal Wash Reagent were cleared as part of the VITROS Immunodiagnostic Products Total T3 Reagent Pack and VITROS Immunodiagnostic Products Total T3 Calibrators 510(k) premarket notification (K964310).

The VITROS Immunodiagnostic and Integrated Systems and common reagents are dedicated specifically for use only with the VITROS Immunodiagnostic Products range of immunoassay products.

8. Substantial Equivalence Information

a. Predicate Device name(s)
IDS-iSYS® 25-Hydroxy Vitamin D Assay

b. Predicate 510(k) number(s)
(K091849)

c. Comparison with predicate:

The VITROS Immunodiagnostic Products 25-OH Vitamin D Total Reagent Pack and Calibrators are substantially equivalent to IDS-iSYS® 25-Hydroxy Vitamin D Assay (K091849).

Table 1 and 2 below present the similarities and differences between the predicate and new device.

Table 1 Comparison of the VITROS® and IDS-iSYS® Vitamin D assays

Similarities		
Item	New Device	Predicate (k091849)
Intended use and indications for use	Same	Quantitative determination of 25-Hydroxyvitamin D to be used in the assessment of Vitamin D sufficiency.
Fundamental Scientific Technology	Same	Immunoassay, solid phase antibody capture
Basic Principle	Same	Direct competitive assay
Detection	Same	Light signal measurement
Instrumentation	Same	Automated instrumentation
Sample Type	Same	Serum

Differences		
Item	New Device	Predicate (k091849)
Antibody	Anti-25 OH D Sheep Monoclonal IgG	Anti-25 OH D Sheep Polyclonal IgG
Measuring Range	12.8- 126 ng/mL	6-126 ng/mL

Table 2 Comparison of the VITROS® and IDS-iSYS® Vitamin D Calibrators

Similarities		
Item	New Device	Predicate (k091849)
Intended use and indications for use	For use in the calibration of the VITROS Systems for the quantitative measurement of total 25-OH vitamin D in human serum.	For use in the calibration of the IDS iSYS System for the quantitative measurement of total 25-OH vitamin D in human serum.
Format	Same	Liquid Ready-to-Use
Calibrator Levels	Same	Two
Storage	Same	Refrigerated

Differences		
Item	New Device	Predicate (k091849)
Calibrator Matrix	Human serum and antimicrobial	Horse Serum in a buffer matrix and sodium azide

9 Performance Testing

9.1 Precision

Precision was evaluated consistent with NCCLS document EP5. Two replicates each of three patient samples and one commercial control sample were tested on two separate occasions per day on at least 20 different days. The experiment was performed using three reagent lots on two different systems. The data presented are a representation of the product performance.

VITROS 3600 Immunodiagnostic System and VITROS 5600 Integrated System

System	Units = [ng/mL]							No. Observ.	No. Days
	Mean [25-OH Vitamin D Total] Conc.	Within-run*		Within-calibration**		Within-lab***			
		SD	CV (%)	SD	CV (%)	SD	CV (%)		
ECi/ECiQ System 1 Lot 1	22.5	1.66	7.4	3.14	14.0	3.43	15.3	80	20
	31.1	2.25	7.2	3.86	12.4	4.13	13.3	80	20
	70.0†	3.86	5.5	5.86	8.4	6.24	8.9	80	20
	121	4.1	3.4	6.1	5.1	6.7	5.5	80	20
ECi/ECiQ System 2 Lot 2	20.7	2.46	12.0	3.32	16.2	3.43	16.4	80	20
	28.1	3.06	11.0	3.34	12.0	3.43	12.1	80	20
	65.0†	5.20	8.1	5.66	8.8	5.94	9.1	80	20
	108	4.1	3.8	5.5	5.2	5.9	5.4	80	20
3600 System 1 Lot 1	22.9	2.26	10.5	2.90	13.5	4.04	16.5	80	20
	31.6	2.66	8.9	3.36	11.2	4.65	14.0	80	20
	72.2†	4.30	6.1	5.73	8.1	6.80	9.2	80	20
	123	4.8	3.9	6.5	5.3	7.4	6.0	80	20
3600 System 1 Lot 3	21.0	3.22	15.3	3.29	15.6	3.32	15.8	80	20
	29.5	3.35	11.3	3.43	11.6	3.62	12.3	80	20
	71.1†	5.93	8.3	6.07	8.5	5.92	8.4	80	20
	120	5.8	4.7	5.9	4.9	5.8	4.8	80	20
5600 System 1 Lot 2	23.5	2.43	10.1	2.95	12.2	2.93	12.8	80	20
	31.9	2.52	7.7	3.22	9.9	3.13	10.1	80	20
	69.4†	3.75	5.3	4.82	6.8	4.39	6.5	80	20
	117	6.1	5.1	6.5	5.4	6.4	5.6	80	20

* **Within-run (repeatability)**. Between Duplicate precision averaged over all runs

** **Within-calibration**. Total precision with weighted components of within-run, between–run and between-day variation

*** **Within-lab**. A measure of the effect of recalibration on total precision, calculated within reagent lot, using data from at least 4 calibrations

† This sample is a commercial quality control fluid. The other samples are human serum samples

System	Units = [nmol/L]							No. Observ.	No. Days
	Mean [25-OH Vitamin D Total] Conc.	Within-run*		Within-calibration**		Within-lab***			
		SD	CV (%)	SD	CV (%)	SD	CV (%)		
ECi/ECiQ System 1 Lot 1	56.3	4.15	7.4	7.85	14.0	8.58	15.3	80	20
	77.8	5.63	7.2	9.65	12.4	10.30	13.3	80	20
	175†	9.7	5.5	14.7	8.4	15.6	8.9	80	20
	303	10.3	3.4	15.3	5.1	16.8	5.5	80	20
ECi/ECiQ System 2 Lot 2	51.8	6.15	12.0	8.30	16.2	8.58	16.4	80	20
	70.3	7.65	11.0	8.35	12.0	8.58	12.1	80	20
	163†	13.0	8.1	14.2	8.8	14.9	9.1	80	20
	270	10.3	3.8	13.8	5.2	14.8	5.4	80	20
3600 System 1 Lot 1	57.3	5.65	10.5	7.25	13.5	10.10	16.5	80	20
	79.0	6.65	8.9	8.40	11.2	11.60	14.0	80	20
	181†	10.8	6.1	14.3	8.1	17.0	9.2	80	20
	308	12.0	3.9	16.3	5.3	18.5	6.0	80	20
3600 System 1 Lot 3	52.5	8.05	15.3	8.23	15.6	8.30	15.8	80	20
	73.8	8.38	11.3	8.58	11.6	9.05	12.3	80	20
	178†	14.8	8.3	15.2	8.5	14.8	8.4	80	20
	300	14.5	4.7	14.8	4.9	14.5	4.8	80	20
5600 System 1 Lot 2	58.8	6.08	10.1	7.38	12.2	7.33	12.8	80	20
	79.8	6.30	7.7	8.05	9.9	7.83	10.1	80	20
	174†	9.4	5.3	12.1	6.8	11.0	6.5	80	20
	293	15.3	5.1	16.3	5.4	16.0	5.6	80	20

* **Within-run (repeatability)**. Between Duplicate precision averaged over all runs
** **Within-calibration**. Total precision with weighted components of within-run, between–run and between-day variation
*** **Within-lab**. A measure of the effect of recalibration on total precision, calculated within reagent lot, using data from at least 4 calibrations
† This sample is a commercial quality control fluid. The other samples are human serum samples

9.2 Linearity

The method was based on CLSI EP6-A ("Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical approach; Approved Guideline"). Two lots of VITROS 25-OH Vitamin D Total Assay (tVitD) were

tested using three VITROS Systems (one VITROS ECi/ECiQ Immunodiagnostic System, one VITROS 3600 Immunodiagnostic System, and one VITROS 5600 Integrated System). Two pools of VITROS 25-OH Vitamin D Total Assay samples were prepared with patient samples and were selected near the extremes of the calibration range. The low pool had an estimated concentration of 6.73 ng/mL. The high pool had an estimated concentration of 175 ng/mL. The low and high concentration pools were sequentially mixed to give 7 further pools of intermediate concentrations.

All results from both Master Lot 1 and 2 and all three VITROS Systems supported a measuring range of 12.8 to 126 ng/mL. Analysis by weighted linear regression indicated that the assay results across the entire claimed range (12.8 to 126 ng/mL) are best fitted by a third order polynomial regression. In all cases, the third order polynomial regression had non-linear significant terms and/or was the best fit for the assay results. The linear regression fitted results deviate less than 15% from the third order polynomial regression. The assay is therefore linear over the entire range from 12.8 to 126 ng/mL.

9.3 Limit of Detection

The Limit of Detection (LoD) for VITROS 25-OH Vitamin D Total Assay is 8.64 ng/mL (21.6 nmol/L), determined consistent with CSLI document EP17 and with proportions of false positives (α) less than 5% and false negatives (β) less than 5%; based on 700 determinations, with 1 blank and 6 low-level samples. The Limit of Blank (LoB) is 4.34ng/mL (10.9 nmol/L). The Limit of Quantitation (LoQ) is 12.8 ng/mL (32.0 nmol/L) as determined by the lowest concentration at which precision design requirements are still met and within the linear range of the assay.

At 12.8ng/mL (32.0 nmol/L), the observed imprecision (%CV) is $\leq$ 20% across lots and analyzers.

9.4 Specificity

Point estimates of the effects of test levels of potential cross reactants and interferents have been made with patient samples near 30 ng/mL and 80 ng/mL Vitamin D. To calculate the % interference or % cross reactivity, the mean value of a solution of each test substance was compared with that of a corresponding "control" in two VITROS 25-OH Vitamin D Total Assay lots. Paricalcitol (Zemplar) interferes with the VITROS 25-OH Vitamin D Total Assay. Of the other compounds tested for interference, none was found to cause a >10% bias at the test concentrations.

Specificity

Substances that do not Interfere

The VITROS 25-OH Vitamin D Total test was evaluated for interference consistent with CLSI document EP7-A2. Of the compounds tested, none was found to cause a bias of >10% with the test at the concentrations indicated at 25-OH Vitamin D concentrations of 30-80 ng/mL(75-200nmol/L).

Compound	Concentration	
Acetaminophen	1324µmol/L	200µg/mL
Acetylsalicylic Acid	3.62mmol/L	65.16mg/dL
Bilirubin (unconjugated)	513µmol/L	30 mg/dL
Bilirubin (conjugated)	356µmol/L	30 mg/dL
Biotin	61.35nmol/L	1.5µg/dL
Hemoglobin (hemolysate)	0.124mmol/L	200 mg/dL
Ibuprofen	0.576mmol/L	12mg/dL
Triolein	33.0mmol/L	3000 mg/dL
Cholesterol	7.91 mmol/L	306 mg/dL
Total Protein	108g/L	10.8g/dL
Triglycerides	5.69 mmol/L	504 mg/dL

The results of the potentially cross-reacting substances listed in the Table below show the % cross-reactivity in the VITROS 25-OH Vitamin D Total assay

Compound	Concentration	Sample 25-OH Vitamin D Concentration		Mean 25-OH Vitamin D Result of Cross-reactant Pool		% Cross-reactivity
		[ng/mL]	[nmol/L]	[ng/mL]	[nmol/L]	
Vitamin D_2 (Ergocalciferol)	100ng/mL	8.81	22.0	9.77	24.4	1.0

Vitamin D_3 (Cholecalciferol)	100ng/mL	8.81	22.0	9.66	24.2	0.9
25-OH Vitamin D_2	100ng/mL	8.10	20.3	113	283	104.9
25-OH Vitamin D_3	100ng/mL	8.10	20.3	107	268	98.9
1,25 $(OH)_2$ Vitamin D_2	0.2ng/mL*	8.81	22.0	10.1	25.3	>100
1,25 $(OH)_2$ Vitamin D_2	0.2ng/mL*	26.8	67.0	28.5	71.3	>100
1,25 $(OH)_2$ Vitamin D_3	0.2ng/mL*	8.10	20.3	8.09	20.2	-5.0
24,25 $(OH)_2$ Vitamin D_2	10ng/mL**	26.8	67.0	30.2	75.5	34.3
24,25 $(OH)_2$ Vitamin D_3	10ng/mL**	7.92	19.8	11.4	28.5	34.8
3-epi 25-OH Vitamin D_3	100ng/mL	7.92	19.8	45.3	113	37.4

*Levels tested were 2x to 4x the typical endogenous levels of analyte. 0.2 ng/mL 1,25 $(OH)_2$ Vitamin D_2 (4 x the upper limit of the reference interval) produced a bias in the measurement of just 1.7 ng/mL at a baseline 25-OH Vitamin D of 30 ng/mL.

**Levels tested were 2x to 4x the typical endogenous levels of analyte

9.5 Method Comparison

The method was consistent with CSLI document EP9-A2-IR ("Method Comparison and Bias Estimation Using Patient Samples"; Approved Guideline - Second Edition) Interim Review.

A minimum of 117 human serum samples were assayed using the VITROS® Immunodiagnostic Products 25-OH Vitamin D Total assay on the VITROS Systems and the *IDS-iSYS*® 25-Hydroxy Vitamin D assay on the IDS-iSYS System All human serum samples were run in singleton on all systems. The highest sample (Sample ID: R204553) was approximately 95% of the top of the measuring range of the VITROS 25-OH Vitamin D Total Assay (i.e. 120 ng/mL). Seven (7) -spiked and one pooled sample were used for this test.

Passing & Bablok Regression was performed for all comparisons. In each case, the VITROS 25-OH Vitamin D Total assay results were plotted as the "y"

variable and those from the IDS-iSYS assay as the "x" variable. For the quantitative comparison, only those data within the measuring range of the compared IDS-iSYS and VITROS assays were analyzed. The measuring range for the VITROS 25-OH Vitamin D Total is 12.8 - 126 ng/mL. The IDS-iSYS measuring range is 6–126 ng/mL. Fourteen (14) samples were below the VITROS 25-OH Vitamin D Total assay's measuring range on the 3600 Integrated system and fifteen (15) samples were below the VITROS 25-OH Vitamin D Total assay's measuring range on the 5600 Integrated system and the ECi/ECiQ Immunodiagnostic system. The parameters of the Passing & Bablok Regressions were used to state the equations for the product claim for testing with the VITROS ECi/ECiQ Immunodiagnostic System, the VITROS 3600 Immunodiagnostic System and the VITROS 5600 Integrated System.

The comparisons of VITROS to IDS-iSYS are as follows:

VITROS 5600 Integrated System 25-OH Vitamin D Total = 0.99 x IDS-iSYS - 5.12 ng/mL, n = 102, r = 0.92. The 95%CI for the slope is 0.86 to 1.12 and for the Intercept is -10.2 to -0.53.

VITROS 3600 Immunodiagnostic System 25-OH Vitamin D Total = 1.08 x IDS-iSYS -7.87 ng/mL, n = 103, r = 0.93. The 95%CI for the slope is 0.96 to 1.22 and for the Intercept is -12.4 to -2.95.

VITROS ECi/ECiQ Immunodiagnostic System 25-OH Vitamin D Total = 0.96 x IDS-iSYS -9.07 ng/mL, n = 102, r = 0.94. The 95%CI for the slope is 0.86 to 1.09 and for the Intercept is -14.2 to -4.69.

9.6 Matrix Comparison

Only serum can be used.

9.7 Reference Range

A study was conducted using 399 apparently healthy adults between the ages of 21–79. Samples came from individuals who live in the North, South and Central regions of the United States and were collected in both summer and winter. These samples were tested using the VITROS 25-OH Vitamin D Total assay and the observed values are summarized below:

Observed Values		
Median 25 OH Vitamin D	33.4 (ng/mL)	83.5(nmol/L)
Observed Range 2.5th to 97.5th Percentile	14.7 to 68.3 (ng/mL)	36.8 – 171 (nmol/L)

9.8 Stability

The VITROS 25-OH Vitamin D Total assay is currently under a stability protocol to evaluate the maximum unopened reagent and calibrator dating.

10. Conclusion

The data presented provide a reasonable assurance that the VITROS Immunodiagnostic Products 25-OH Vitamin D Total Reagent Pack and Calibrators are safe and effective for the stated intended uses and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 15, 2013

Ortho-Clinical Diagnostics, Inc.
c/o Eric Schaeffer
100 Indigo Creek Dr.
Rochester, NY 14626-5101

Re: k121608
Trade/Device Name: VITROS® Immunodiagnostic Products 25-OH Vitamin D Total Reagent Pack
VITROS® Immunodiagnostic Products 25-OH Vitamin D Total Calibrators
Regulation Number: 21 CFR 862.1825
Regulation Name: Vitamin D test system
Regulatory Class: II
Product Code: MRG, JIT
Dated: January 18, 2013
Received: January 22, 2013

Dear Mr. Schaeffer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k121608

Device Name: VITROS® Immunodiagnostic Products 25-OH Vitamin D Total Assay

Indications for Use:

VITROS® Immunodiagnostic Products 25-OH Vitamin D Total Reagent Pack:

For *in vitro* diagnostic use only

For the quantitative measurement of total 25-OH vitamin D in human serum using the VITROS ECi/ECiQ Immunodiagnostic Systems, the VITROS 3600 Immunodiagnostic System and the VITROS 5600 Integrated System.

The results of the VITROS 25-OH Vitamin D Total assay are used in the assessment of Vitamin D sufficiency. Assay results may be used in conjunction with other clinical or laboratory data to assist the clinician in patient management.

VITROS® Immunodiagnostic Products 25-OH Vitamin D Total Calibrators:

For *in vitro* diagnostic use only.

For use in the calibration of the VITROS ECi/ECiQ Immunodiagnostic Systems, the VITROS 3600 Immunodiagnostic Systems and the VITROS 5600 Integrated System for the quantitative measurement of total 25-OH vitamin D in human serum.

Prescription Use X		Over-The-Counter Use
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

Ruth A. Chesler

Division Sign-Off
Office of In Vitro Devices and Radiologic Health

510(k) k121608